Appendix 1 - Pending Claims

35. (Amended) An immediate-release fenofibrate composition comprising granulates, wherein said granulates comprise inert hydrosoluble carrier particles, which are either isolated or agglomerated together, and micronized fenofibrate particles with a particle size below 20 μm in admixture with a hydrophilic polymer adhering onto the surface of the inert hydrosoluble carrier particles, wherein the granulates optionally comprise an outer coating or are optionally agglomerated.

36. The composition of claim 35, wherein the inert hydrosoluble carrier particles have a particle size between 50 and 500 microns.

37. The composition of claim 36, wherein the inert hydrosoluble carrier particles have a particle size between 100 and 400 microns.

38. The composition of claim 37, wherein the inert hydrosoluble carrier particles are comprised of lactose.

39. (Amended) The composition of claim 35, wherein the granulates are produced by a process comprising spraying a suspension containing the fenofibrate particles and the hydrophilic polymer onto the inert hydrosoluble carrier particles.

40. The composition of claim 39, wherein the granulates are produced by a fluidized-bed granulation technique.

41. (Amended) The composition of claim 40, wherein the fluidized-bed granulation technique comprises spraying a suspension containing the fenofibrate particles and the hydrophilic polymer, and optionally a surfactant, onto the inert hydrosoluble carrier particles in a fluidized bed.

42. The composition of claim 35, wherein the immediate-release fenofibrate composition is in the form of a tablet.

43. The composition of claim 35, further comprising a surfactant with the fenofibrate particles and the hydrophilic polymer.

44. The composition of claim 35, wherein the hydrophilic polymer is polyvinylpyrrolidone.

B4

45. (Amended) The composition according to claim 43, wherein the surfactant is sodium laurylsulfate.

46. An immediate-release fenofibrate composition comprising granulates, said granulates comprising inert hydrosoluble carrier particles having a particle size between 100 and 400 microns, which are either isolated or agglomerated together, and fenofibrate particles with a particle size below 20 μm in admixture with a hydrophilic polymer, adhering to the surface of the inert hydrosoluble carrier particles, wherein the granulates optionally comprise an outer coating or are optionally agglomerated, wherein the granulates are produced by fluidized-bed granulation which comprises spraying a suspension of fenofibrate particles with the hydrophilic polymer, and optionally a surfactant, onto the inert hydrosoluble carrier particles in a fluidized bed.

B5

47. (Amended) The composition of claim 46, wherein the inert hydrosoluble carrier particles are comprised of lactose.

48. The composition of claim 46, wherein the immediate-release fenofibrate composition is in the form of a tablet.

49. The composition of claim 46, further comprising a surfactant with the fenofibrate particles and the hydrophilic polymer.

50. The composition of claim 46, wherein the hydrophilic polymer is polyvinylpyrrolidone.

51. The composition of claim 49, wherein the surfactant is sodium laurylsulfate.

52. (Amended) A method for preparing the composition of claim 35, comprising the steps of:

B6

(a) preparing a fenofibrate suspension in micronized form with a particle size below 20 μm in a solution of a hydrophilic polymer, and optionally a surfactant;

(b) spraying the fenofibrate suspension from step (a) to inert hydrosoluble carrier particles to form granules; and

(c) optionally coating the granules from step (b) with one or several phase(s) or layer(s).

53. The method of claim 52, wherein step (b) is carried out in a fluidized-bed granulator.

54. The method of claim 52, further comprising compressing the product of step (b) or compressing the product of step (c).

55. A method for preparing the composition of claim 46, comprising the steps of:

(a) preparing a fenofibrate suspension in micronized form with a particle size below 20 μm in a solution of a hydrophilic polymer, and optionally a surfactant;

(b) spraying the fenofibrate suspension from step (a) to inert hydrosoluble carrier particles having a particle size between 100 and 400 microns to form granules in a fluidized-bed granulator; and

(c) optionally coating the granules from step (b) with one or several phase(s) or layer(s).

56. The method of claim 55, further comprising compressing the product of step (b) or compressing the product of step (c).

57. (New) The composition of claim 35, wherein the micronized fenofibrate particles have a particle size of less than or equal to 10 μm.

58. (New) The composition of claim 46, wherein the micronized fenofibrate particles have a particle size of less than or equal to 10 μm.

59. (New) The composition of claim 35, wherein the inert hydrosoluble carrier particles are comprised of lactose, saccharose, hydrolyzed starch, or a mixture thereof.

60. (New) The composition of claim 46, wherein the inert hydrosoluble carrier particles are comprised of lactose, saccharose, hydrolyzed starch, or a mixture thereof.

61. (New) The composition of claim 35, wherein the hydrophilic polymer is polyvinylpyrrolidone, poly(vinyl alcohol), hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, or a mixture thereof.

62. (New) The composition of claim 46, wherein the hydrophilic polymer is polyvinylpyrrolidone, poly(vinyl alcohol), hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, or a mixture thereof.

63. (New) The composition of claim 43, wherein the surfactant is sodium lauryl sulfate, monooleate polyoxyethylene sorbitane, monolaurate polyoxyethylene sorbitane, monopalmitate polyoxyethylene sorbitane, monostearate polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearylic alcohol, cetostearylic alcohol, cholesterol, polyoxyethylene ricin oil, a polyoxyethylene fatty acid glyceride, a poloxamer, or a mixture thereof.

64. (New) The composition of claim 49, wherein the surfactant is sodium lauryl sulfate, monooleate polyoxyethylene sorbitane, monolaurate polyoxyethylene sorbitane, monopalmitate polyoxyethylene sorbitane, monostearate polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearylic alcohol, cetostearylic alcohol, cholesterol, polyoxyethylene ricin oil, a polyoxyethylene fatty acid glyceride, a poloxamer, or a mixture thereof.

65. (New) The composition of claim 35, wherein the weight ratio of micronized fenofibrate to hydrophilic polymer is between 1:10 and 4:1.

66. (New) The composition of claim 46, wherein the weight ratio of micronized fenofibrate to hydrophilic polymer is between 1:10 and 4:1.

67. (New) The composition of claim 35, wherein the inert hydrosoluble carrier is present in an amount of 10 to 80% by weight, the micronized fenofibrate is present in an amount of 5 to 50% by weight, and the hydrophilic polymer is present in an amount of 20 to 60% by weight.

68. (New) The composition of claim 67, wherein the inert hydrosoluble carrier is present in an amount of 20 to 50% by weight, the micronized fenofibrate is present in an amount of 20 to 45% by weight, and the hydrophilic polymer is present in an amount of 25 to 45% by weight.

69. (New) The composition of claim 46, wherein the inert hydrosoluble carrier is present in an amount of 10 to 80% by weight, the micronized fenofibrate is present in an amount

of 5 to 50% by weight, and the hydrophilic polymer is present in an amount of 20 to 60% by weight.

70. (New) The composition of claim 69, wherein the inert hydrosoluble carrier is present in an amount of 20 to 50% by weight, the micronized fenofibrate is present in an amount of 20 to 45% by weight, and the hydrophilic polymer is present in an amount of 25 to 45% by weight.

71. (New) The composition of claim 43, wherein the surfactant is present in an amount of 0.1 to 10% by weight.

72. (New) The composition of claim 49, wherein the surfactant is present in an amount of 0.1 to 10% by weight.

73. (New) The composition of claim 35, wherein the composition has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopocia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80.

74. (New) The composition of claim 35, wherein the composition has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopocia, in a dissolution medium constituted by water with 0.025 M sodium lauryl sulfate.

75. (New) The composition of claim 46, wherein the composition has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopocia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80.

76. (New) The composition of claim 46, wherein the composition has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopocia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80.

77. (New) A fenofibrate composition comprising granules, wherein the granules comprise:

(i) hydrosoluble carrier particles; and

(ii) one or more layers comprised of micronized fenofibrate dispersed throughout a hydrophilic polymer, wherein the one or more layers are deposited on the hydrosoluble carrier particles.

78. (New) The composition of claim 77, wherein the hydrosoluble carrier particles are lactose, saccharose, hydrolyzed starch, or a mixture thereof.

79. (New) The composition of claim 77, wherein the hydrophilic polymer is polyvinyl pyrrolidone, poly(vinylalcohol), hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose; gelatin, or a mixture thereof.

80. (New) The composition of claim 77, wherein the hydrosoluble carrier particles are lactose and the hydrophilic polymer is polyvinylpyrrolidone.

81. (New) The composition of claim 77, further comprising a surfactant.

82. (New) The composition of claim 81, wherein the surfactant is dispersed throughout the hydrophilic polymer.

83. (New) The composition of claim 82, wherein the surfactant is sodium lauryl sulfate, monooleate polyoxyethylene sorbitane, monolaurate polyoxyethylene sorbitane, monopalmitate polyoxyethylene sorbitane, monostearate polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearylic alcohol, cetostearylic alcohol, cholesterol, polyoxyethylene ricin oil, a polyoxyethylene fatty acid glyceride, a poloxamer, or a mixture thereof.

84. (New) The composition of claim 83, wherein the surfactant is sodium lauryl sulfate.

85. (New) The composition of claim 84, wherein the hydrosoluble carrier particles are lactose and the hydrophilic polymer is polyvinylpyrrolidone.

86. (New) The composition of claim 77, wherein the hydrosoluble carrier particles are present in an amount from 10 to 80% by weight ; the micronized fenofibrate is present in an

amount from 5 to 50% by weight, and the hydrophilic polymer is present in an amount from 20 to 60% by weight.

87. (New) The composition of claim 86, wherein the hydrosoluble carrier particles are present in an amount from 20 to 50% by weight ; the micronized fenofibrate is present in an amount from 20 to 45% by weight ; and the hydrophilic polymer is present in an amount from 25 to 45% by weight.

88. (New) The composition of claim 81, wherein the surfactant is present in an amount from 0.1 to 3% by weight.

89. (New) The composition of claim 77, wherein the composition has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopocia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80.

90. (New) The composition of claim 77, wherein the composition has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopocia, in a dissolution medium constituted by water with 0.025 M sodium lauryl sulfate.

Appendix 2 - Amendments to Claims

35. (Amended) An immediate-release fenofibrate composition comprising granulates, wherein said granulates comprise inert hydrosoluble carrier particles, which are either isolated or agglomerated together, and micronized fenofibrate particles with a particle size below 20 μm in admixture with a hydrophilic polymer adhering [to] onto the surface of the inert hydrosoluble carrier particles, wherein the granulates optionally comprise an outer coating or are optionally agglomerated.

39. (Amended) The composition of claim 35, wherein the granulates are produced by a process comprising spraying a suspension [of] containing the fenofibrate particles and the hydrophilic polymer onto the inert hydrosoluble carrier particles.

41. (Amended) The composition of claim 40, wherein the fluidized-bed granulation technique comprises spraying a suspension [of] containing the fenofibrate particles [with] and the hydrophilic polymer, and optionally a surfactant, onto the inert hydrosoluble carrier particles in a fluidized bed.

45. (Amended) The composition according to claim [45,] 43, wherein the surfactant is sodium laurylsulfate.

47. (Amended) The composition of claim [47,] 46, wherein the inert hydrosoluble carrier particles are comprised of lactose.

52. (Amended) A method for preparing the composition of claim [1,] 35, comprising the steps of:

(a) preparing a fenofibrate suspension in micronized form with a particle size below 20 μm in a solution of a hydrophilic polymer, and optionally a surfactant;

(b) spraying the fenofibrate suspension from step (a) to inert hydrosoluble carrier particles to form granules; and

(c) optionally coating the granules from step (b) with one or several phase(s) or layer(s).

57. (New) The composition of claim 35, wherein the micronized fenofibrate particles have a particle size of less than or equal to 10 μm.

58. (New) The composition of claim 46, wherein the micronized fenofibrate particles have a particle size of less than or equal to 10 μm.

59. (New) The composition of claim 35, wherein the inert hydrosoluble carrier particles are comprised of lactose, saccharose, hydrolyzed starch, or a mixture thereof.

60. (New) The composition of claim 46, wherein the inert hydrosoluble carrier particles are comprised of lactose, saccharose, hydrolyzed starch, or a mixture thereof.

61. (New) The composition of claim 35, wherein the hydrophilic polymer is polyvinylpyrrolidone, poly(vinyl alcohol), hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, or a mixture thereof.

62. (New) The composition of claim 46, wherein the hydrophilic polymer is polyvinylpyrrolidone, poly(vinyl alcohol), hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose, gelatin, or a mixture thereof.

63. (New) The composition of claim 43, wherein the surfactant is sodium lauryl sulfate, monooleate polyoxyethylene sorbitane, monolaurate polyoxyethylene sorbitane, monopalmitate polyoxyethylene sorbitane, monostearate polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearylic alcohol, cetostearylic alcohol, cholesterol, polyoxyethylene ricin oil, a polyoxyethylene fatty acid glyceride, a poloxamer, or a mixture thereof.

64. (New) The composition of claim 49, wherein the surfactant is sodium lauryl sulfate, monooleate polyoxyethylene sorbitane, monolaurate polyoxyethylene sorbitane, monopalmitate polyoxyethylene sorbitane, monostearate polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearylic alcohol, cetostearylic alcohol, cholesterol, polyoxyethylene ricin oil, a polyoxyethylene fatty acid glyceride, a poloxamer, or a mixture thereof.

65. (New) The composition of claim 35, wherein the weight ratio of micronized fenofibrate to hydrophilic polymer is between 1:10 and 4:1.

66. (New) The composition of claim 46, wherein the weight ratio of micronized fenofibrate to hydrophilic polymer is between 1:10 and 4:1.

67. (New) The composition of claim 35, wherein the inert hydrosoluble carrier is present in an amount of 10 to 80% by weight, the micronized fenofibrate is present in an amount of 5 to 50% by weight, and the hydrophilic polymer is present in an amount of 20 to 60% by weight.

68. (New) The composition of claim 67, wherein the inert hydrosoluble carrier is present in an amount of 20 to 50% by weight, the micronized fenofibrate is present in an amount of 20 to 45% by weight, and the hydrophilic polymer is present in an amount of 25 to 45% by weight.

69. (New) The composition of claim 46, wherein the inert hydrosoluble carrier is present in an amount of 10 to 80% by weight, the micronized fenofibrate is present in an amount of 5 to 50% by weight, and the hydrophilic polymer is present in an amount of 20 to 60% by weight.

70. (New) The composition of claim 69, wherein the inert hydrosoluble carrier is present in an amount of 20 to 50% by weight, the micronized fenofibrate is present in an amount of 20 to 45% by weight, and the hydrophilic polymer is present in an amount of 25 to 45% by weight.

71. (New) The composition of claim 43, wherein the surfactant is present in an amount of 0.1 to 10% by weight.

72. (New) The composition of claim 49, wherein the surfactant is present in an amount of 0.1 to 10% by weight.

73. (New) The composition of claim 35, wherein the composition has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopocia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80.

74. (New) The composition of claim 35, wherein the composition has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopocia, in a dissolution medium constituted by water with 0.025 M sodium lauryl sulfate.

75. (New) The composition of claim 46, wherein the composition has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopocia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80.

76. (New) The composition of claim 46, wherein the composition has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopocia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80.

77. (New) A fenofibrate composition comprising granules, wherein the granules comprise:

(i) hydrosoluble carrier particles; and

(ii) one or more layers comprised of micronized fenofibrate dispersed throughout a hydrophilic polymer, wherein the one or more layers are deposited on the hydrosoluble carrier particles.

78. (New) The composition of claim 77, wherein the hydrosoluble carrier particles are lactose, saccharose, hydrolyzed starch, or a mixture thereof.

79. (New) The composition of claim 77, wherein the hydrophilic polymer is polyvinyl pyrrolidone, poly(vinylalcohol), hydroxypropylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose; gelatin, or a mixture thereof.

80. (New) The composition of claim 77, wherein the hydrosoluble carrier particles are lactose and the hydrophilic polymer is polyvinylpyrrolidone.

81. (New) The composition of claim 77, further comprising a surfactant.

82. (New) The composition of claim 81, wherein the surfactant is dispersed throughout the hydrophilic polymer.

83. (New) The composition of claim 82, wherein the surfactant is sodium lauryl sulfate, monooleate polyoxyethylene sorbitane, monolaurate polyoxyethylene sorbitane, monopalmitate polyoxyethylene sorbitane, monostearate polyoxyethylene sorbitane, sodium

dioctylsulfosuccinate, lecithin, stearylic alcohol, cetostearylic alcohol, cholesterol, polyoxyethylene ricin oil, a polyoxyethylene fatty acid glyceride, a poloxamer, or a mixture thereof.

84. (New) The composition of claim 83, wherein the surfactant is sodium lauryl sulfate.

85. (New) The composition of claim 84, wherein the hydrosoluble carrier particles are lactose and the hydrophilic polymer is polyvinylpyrrolidone.

86. (New) The composition of claim 77, wherein the hydrosoluble carrier particles are present in an amount from 10 to 80% by weight ; the micronized fenofibrate is present in an amount from 5 to 50% by weight, and the hydrophilic polymer is present in an amount from 20 to 60% by weight.

87. (New) The composition of claim 86, wherein the hydrosoluble carrier particles are present in an amount from 20 to 50% by weight ; the micronized fenofibrate is present in an amount from 20 to 45% by weight ; and the hydrophilic polymer is present in an amount from 25 to 45% by weight.

88. (New) The composition of claim 81, wherein the surfactant is present in an amount from 0.1 to 3% by weight.

89. (New) The composition of claim 77, wherein the composition has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopocia, in a dissolution medium constituted by water with 2 % by weight polysorbate 80.

90. (New) The composition of claim 77, wherein the composition has a dissolution of at least 10 % in 5 minutes, 20 % in 10 minutes, 50 % in 20 minutes and 75 % in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopocia, in a dissolution medium constituted by water with 0.025 M sodium lauryl sulfate.